DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 1, 2017

MedCom GmbH
% Mr. Johannes Messow
Quality Manager
Rundeturmstr. 50
Darmstadt, Hessen 64283
GERMANY

Re: K163119
Trade/Device Name: NaviSuite SSI Edition
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 3, 2017
Received: April 3, 2017

Dear Mr. Messow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163119

Device Name
NaviSuite SSI Edition

Indications for Use *(Describe)*
The NaviSuite SSI Edition is used to support a clinical ultra-sound session and follow percutaneous procedure by means of providing additional real-time image information from a 2nd modality like CT or MR or US or its combination with the possibility to plan the ideal treatment procedure. The second modality or their combinations are acquired and 3D is generated inside the software permitting the anatomical correlation with the patient position.

"The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information."

"The 2nd modality image only should not be used for diagnostic purposes."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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V. 510(k) Summary of Safety and Effectiveness

A. Submitter

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Fax:	+49 (6151) 95147-20
Contact:	Mr. Johannes Messow jmessow@medcom-online.de
Date:	April 26, 2017

B. Device

Trade Name:	NaviSuite SSI Edition	
Common name:	SuperSonic Navigator	
Classification:	Regulatory Class:	II
	Product Code:	LLZ / System, Image Processing, Radiological
	CFR Section:	892.2050
	Panel:	Radiology

C. Predicate Devices

Device trade name:	MIM 3.5 (CIRCA)
510(k) number:	K052379
Company name:	MIMVISTA CORP.
Classification Number:	892.2050
Classification:	Class II
Product code:	LLZ

Device trade name:	MyLabClass C 6250 MyLabTwice 6200
510(k) number:	K153277
Company name:	Esaote S.P.A.
Classification Number:	892.1550
Classification:	Class II
Product code:	IYN
Subsequent codes:	ITX, IYO

D. Reason for Submission

New device application

E. Standards

1. ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General I (QS/RM))

2. IEC 62304:2006, Medical Device Software - Software Life Cycle Processes. (Software/Informatics)

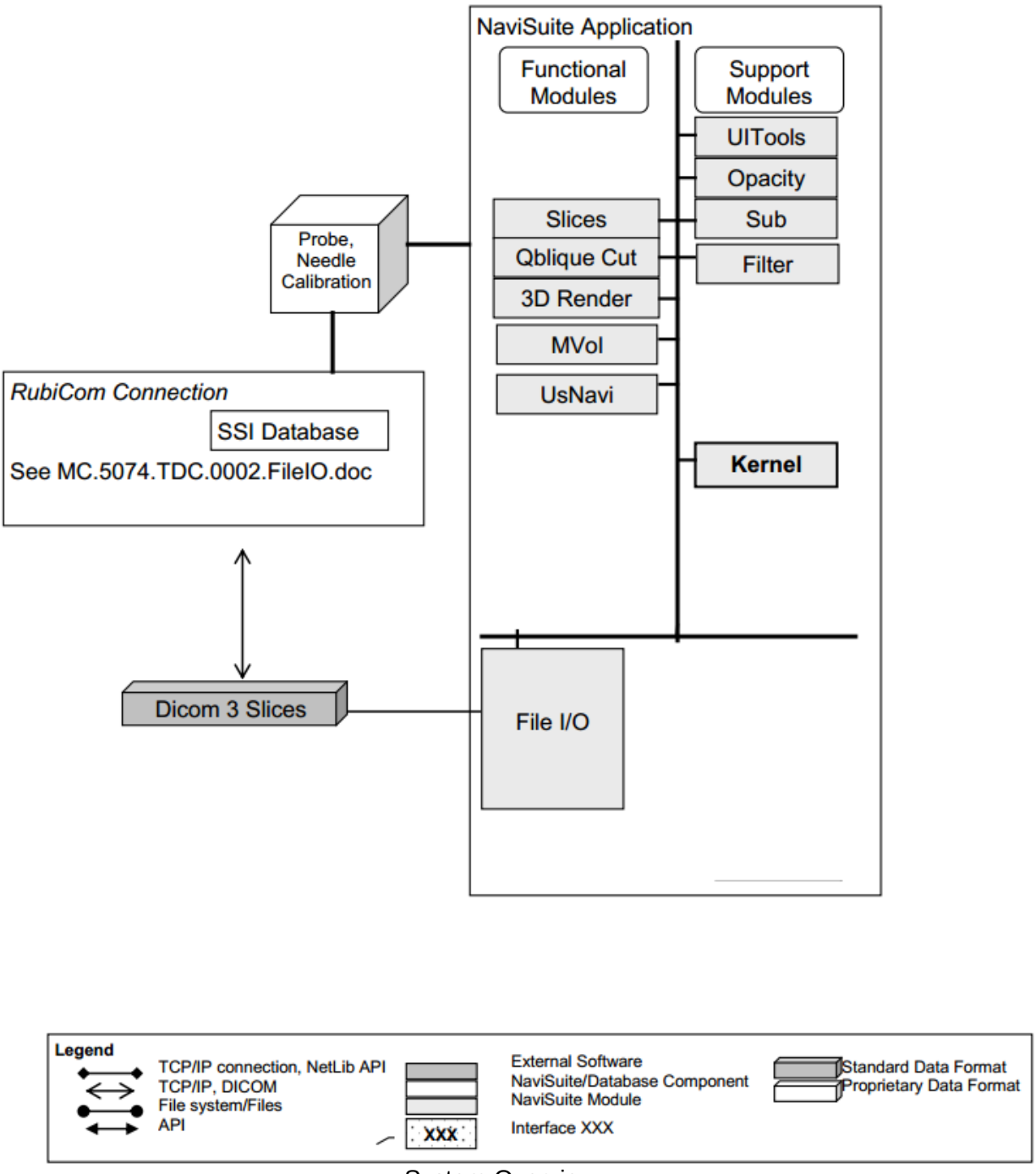
F. Description

NaviSuite SSI Edition 0.9.10 is a medical product to support a clinical ultrasound session and follow percutaneous procedure by means of providing additional real-time image information from a 2nd modality like CT or MR or US or its combination with the possibility to plan the ideal treatment procedure. The second modality or their combinations are acquired and a 3D is generated inside the software permitting the anatomical correlation with the patient position.
By using the 2nd modality image the user gains security in assessing the morphology of the ultrasound image and obtains a virtual feed-back on the procedure provided by the virtual percutaneous tool position enabled by a dedicated receiver, its treatment region delineated by custom tables and a dedicated computation in 3D of the target region.
The 2nd modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient probably not congruent with the current (real) patient situation and shall therefore always been seen as an additional source of information.

NaviSuite SSI Edition is a software designed for use together with an ultrasound device:

Device	Type	510(k) / registration number
System, Imaging, Pulsed Doppler, Ultrasonic	AIXPLORER	K142100

This hardware device is legally marketed in the US as listed in the table above.



System Overview

G. Indications for Use

The NaviSuite SSI Edition is used to support a clinical ultra-sound session and follow percutaneous procedure by means of providing additional real-time image information from a 2nd modality like CT or MR or US or its combination with the possibility to plan the ideal treatment procedure. The second modality or their combinations are acquired and 3D is generated inside the software permitting the anatomical correlation with the patient position.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The 2nd modality image only should not be used for diagnostic purposes.

NaviSuite SSI Edition is intended for prescription use.

H. Intended Use

The main purpose of the medical product NaviSuite SSI Edition is to support a clinical ultra-sound session and follow percutaneous procedure by means of providing additional real-time image information from a 2nd modality like CT or MR or US or its combination with the possibility to plan the ideal treatment procedure. The second modality or their combinations are acquired and 3D is generated inside the software permitting the anatomical correlation with the patient position.

By using the 2nd modality image the user gains security in assessing the morphology of the ultrasound image and obtains a virtual feed-back on the procedure provided by the virtual percutaneous tool position enabled by a dedicated receiver, its treatment region delineated by custom tables and a dedicated computation in 3D of the target region.

The 2nd modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient probably not congruent with the current (real) patient situation and shall therefore always been seen as an additional source of information.

NaviSuite SSI Edition works in Virtual Biopsy mode also without 2nd modality data. In this case needle guidance is shown as an overlay over the real-time US image. The user can ad-just the entry angle and trajectory of the needle before doing percutaneous procedure.

NaviSuite SSI Edition system should only be operated by trained personnel who are familiar with its user manual and the operation

The 2nd modality image only should not be used for diagnostic purposes.

The product NaviSuite SSI Edition was developed by MedCom in cooperation with SSI (France).

I. Technological Comparison to Predicate Devices

The device NaviSuite SSI Edition is substantially equivalent to the predicate device MyLabTwice 6200 (K153277).

It is the same software used in the MyLabTwice 6200 device which was ported to the LINUX operating system of the AIXPLORER ultrasound device. Differences exist in the hardware and the user interfaces. In comparison to MyLabTwice, the NaviSuite software receives the live US image through a shared memory channel where in the MyLabTwice it is grabbed by a frame grabber card. In contrast to the MyLabTwice solution, the NaviSuite SSI Edition does not contain a planning environment and the contouring possibilities have been reduced to defining a ball target at places of interest instead of freehand contouring used in the MyLabTwice device.

MIM 3.5 (CIRCA)

The MIM 3.5 and NaviSuite SSI Edition software can load and display DICOM datasets. The DICOM files are written following a standard which every DICOM compliant software has to follow in order to parse the data. Both software order the slices based on their spatial position and orientation to generate a 3D object of the scanned body region and can compute and visualize virtual cuts and slices through the 3D object.

J. Non-clinical Performance Data

Non-clinical verification and validation software tests were conducted to confirm that NaviSuite SSI Edition meets its intended use and is safe and effective.

System Accuracy Test:
The software cannot determine the accuracy of the treatment procedure. The Therapist or Physician is responsible for verifying the correctness of the registration. For this means the software offers side by side and overlay views (with a real-time US image).

Needle navigation was tested using a CIRS Abdominal Phantom to confirm the software projected virtual needle position over the real time US image.

Tracking Quality Test:
The system can detect low sensor tracking quality and is able to show if the tracking is distorted (for example by metallic objects etc.).

Tests for verifying the tracking accuracy and senor in range status have been carried out.

Statement from the User Manual about the systems accuracy:

2. Security

It is not admitted to ground a diagnosis just on the results of NaviSuite. In particular the displayed image of the 2nd modality shall never be used as a standalone source for assessments since it represents computed and thus artificial information. MedCom is not engaging in any responsibility for indirect harms due to the use and evaluation of diagnosis data furnished by NaviSuite.

6. System Accuracy

2nd Modality Image Display

The system accuracy concerning the matching between the ultrasound image and the 2nd modality image depends highly on the registration process and the condition of the patient compared to the situation when the 2nd modality (i.e. the CT scan) has been acquired. This also includes the breathing of the patient. Thus, please be aware that the current patient breath state should be comparable to the one during the 2nd modality acquisition.

However, from the technical point of view an "overlapping" accuracy of at least 5mm can be achieved under the presumption that the registration has been done with an overall error better than 5mm.

K. Conclusion

Based on the information provided in this Premarket Notification MedCom concludes that NaviSuite SSI Edition is as safe and effective and substantially equivalent to the predicate devices described herein.